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*Producers of Quality
Nonprescription Medicines and
Dietary Supplements for Self-Care*

CONSUMER HEALTHCARE PRODUCTS ASSOCIATION*Formerly Nonprescription Drug Manufacturers Association*

October 27, 1999

Christine J. Lewis
Center for Food Safety and Applied Nutrition (HFS-451)
Food and Drug Administration
200 C St., SW
Washington, DC 20204

**RE: Docket No. 91N-0103 Health Claims for Omega-3 Fatty Acids
and Coronary Heart Disease - REQUEST FOR EXTENSION**

Dear Ms. Lewis;

The Consumer Healthcare Products Association's Omega-3 Fatty Acids Health Claim Task Group is preparing a response to the Food and Drug Administration's call for scientific data, research study results, and other related information on the relationship between omega-3 fatty acids and coronary heart disease. This notice was published on September 8, 1999 in the *Federal Register*.

Since FDA's last action on this topic in 1992, a significant body of information related to the relationship of omega-3 fatty acids and coronary heart disease has been developed. Literature searches have identified over 1,100 papers published examining the efficacy or safety of this relationship. After examination and evaluation of the searches, we have identified approximately 150 reports that need to be reviewed and submitted to the agency in an organized format to support the relationship. This information is critical to the agency as it reviews the omega-3 fatty acid - coronary heart disease relationship.

While we are making an earnest attempt to compile the information, it is time consuming to retrieve, review, summarize and organize the information, and we anticipate that it will be difficult to complete the task by FDA's 75 day (November 22) deadline. As we draw closer to the agency's deadline, it has come to our attention that the American Heart Association meeting takes place November 6 through 11, 1999. All but one of our expert cardiovascular consultants from whom we plan to obtain input on our submission will be unavailable to us during the week of the AHA meeting. We would like to submit a thorough, integrated, and concise summary of the large body of newly available information with appropriate collaborative input from our well-recognized experts. We therefore request that the agency extend the comment period for four weeks to December 20, 1999 and allow 102 days to enable us to include all of the necessary information.

91N-0103

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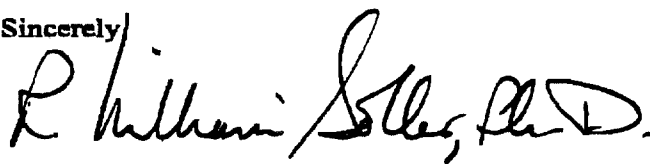
Ms. Christine J. Lewis

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Thank you for your consideration of this request which if granted, will help us provide the agency with useful information as it considers the relationship of omega-3 fatty acids and coronary heart disease. Seventy-five days to evaluate and develop an integrated summary of 150 reports is simply insufficient time for this important effort.

Sincerely,



R. William Soller, Ph.D.

Senior Vice President

and Director of Science & Technology

cc: Dr. Beth Yetley
Mr. Joseph Levitt
Dockets Management Branch

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